UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA NEUROSCIENCE, INC.,

and

YEDA RESEARCH AND DEVELOPMENT CO. LTD.,

Plaintiffs,

-against-

SANDOZ, INC., SANDOZ INTERNATIONAL GMBH, NOVARTIS AG,

and

MOMENTA PHARMACEUTICALS, INC.,

Defendants.

Civil Action No. 08 CV 7611 (BSJ)(AJP)

ECF Case

MEMORANDUM OF LAW IN SUPPORT OF SANDOZ INC.'S AND MOMENTA PHARMACEUTICALS, INC.'S OBJECTIONS TO EVIDENCE AND MOTION TO STRIKE THE EXPERT DECLARATIONS OF DR. GREGORY GRANT AND DR. PAUL DUBIN FROM PLAINTIFFS' OPPOSITION TO MOTION FOR SUMMARY JUDGMENT OF INDEFINITENESS

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(FILED UNDER SEAL)

TABLE OF CONTENTS

TABLE OF CONTENTS
(continued)

Page

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES
(continued)

Page

I. INTRODUCTION

A District Court acts as a "gatekeeper" to ensure that all expert testimony meets the standards for admissibility. Expert testimony must be both relevant and reliable under the well-known requirements established by the Supreme Court in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). To be reliable, expert testimony cannot conflict with the expert's deposition testimony. Here, Teva's opposition to summary judgment relies on expert opinion testimony that fails to meet these standards for admissibility. Defendants hereby object to and move to exclude the declarations of Dr. Gregory Grant and Dr. Paul Dubin from this Court's resolution of the currently pending motion for summary judgment of indefiniteness.

Sandoz Inc.'s and Momenta Pharmaceuticals, Inc.'s (collectively "Sandoz's") summary judgment motion identifies three straightforward reasons why Teva's patent claims are indefinite. First, it is undisputed that Teva's patents do not expressly disclose the *type* of molecular weight average recited in the claims. Second, it is undisputed that the patents' general disclosure of size exclusion chromatography ("SEC") only provides measurements *relative* to the specific calibration *standards* used, and the patents do not disclose the specific calibration standards for determining the claimed molecular weights. Third, it is undisputed that Teva's patents do not disclose the *conditions* used for determining the claimed molecular weights. Each of these deficiencies, standing alone, renders Teva's claims indefinite, because without this critical information, a person of ordinary skill could not meaningfully comprehend Teva's claims either to practice the alleged invention or to assess potential infringement liability.

Both Dr. Grant and Dr. Dubin base their opinions on incorrect assumptions about how molecular weight is determined according to the patents. Their assumptions conflict with the facts of the patentee's own work leading to the patents – work they admit they know nothing about. Their testimony fails to address the relevant question: How can persons of skill in the art

know they have produced "copolymer-1" meeting the molecular weight limitations of the patents?

[redacted]

The defects in Teva's expert declarations are pervasive and fundamental. They go beyond credibility, and trigger the Court's responsibility under *Daubert* to police junk science.

II. BACKGROUND

A. Size Exclusion Chromatography

1. SEC Results Can Substantially Differ Depending on the Calibration Standards and Conditions Used to Determine Molecular Weight.

As its name implies, size exclusion chromatography ("SEC") separates molecules on the basis of their size. These size measurements can be equated to molecular mass or "weight." However, there are many different choices that must be made in setting up an SEC experiment, including which standards the sample will be compared against and which conditions will allow correct comparison between the relative sizes of the standards and the sample to correctly determine their "weights." Different choices result in different numerical values for "molecular weight." It is therefore common practice in the scientific community to report the specific standards and conditions that were used to measure a particular "molecular weight" value.

(Declaration of Karen L. Hagberg in Support of Defendants' Motion to Strike Teva's Expert Declarations ("Hagberg Decl."), Ex. 1, 10/28/09 Grant Depo. at 194:14-195:10.) Without this information, a comparison of "molecular weight" values is meaningless.

a. SEC Analysis Only Provides Information Relative to the Specific Standards Used.

In SEC analysis, well-characterized standards are used to generate a calibration curve to determine molecular weight by comparing the standards to the unknown sample. (Hagberg Decl., Ex. 2, B. Trathnigg, 20 *Prog. Polym. Sci.* 615, 629 (1995).) SEC analysis can *only* provide molecular weight values relative to the standards selected, and those values lack significance outside that specific context. (*Id.*) This issue is magnified for materials such as copolymer-1 that had no known standards in 1994. For example, a 1995 Teva memo states that commercially available standards could *not* be used for accurate molecular weight analysis of copolymer-1. (Hagberg Decl., Ex. 3, Teva 1995 memo at TEV000989752.) That memo also states that, even when copolymer-1 is used as the calibration standard, "the calculated molecular weight averages are at best an approximation relative to the standard used." (*Id.* at TEV000989759.) Precise information about the choices *made for the patents* is therefore necessary for understanding the molecular weight values recited in Teva's patent claims.

b. "Universal Calibration" Is Not Always Valid, and Was Openly Questioned and Criticized in 1994.

[redacted]

[redacted] "Universal calibration" is an alternative SEC approach that attempts to correct for the differences between commercial standards and the samples being tested by assessing a polymer's molecular weight as a function of intrinsic viscosity. (Hagberg Decl., Ex. 4, 2/2/10 Grant Depo. at 27:10-28:7; Ex. 5, Dubin Depo. at 15:9-17.). This approach suffers from its own difficulties and drawbacks. For example, universal calibration cannot

differentiate between two polymers having the same intrinsic viscosity but different molecular weights. (Hagberg Decl., Ex. 2 at 630.) Further, universal calibration frequently fails for polymers with molecular weights below 10 kDa, the same range as Teva's asserted claims. (Hagberg Decl., Ex. 6, P. Wyatt, 272 *Analyt. Chimica Acta* 1, 37 (1993); Hagberg Decl., Ex. 7, P. Dubin et al., 312 *Analyt. Biochem.* 33, 39 (2003).) Moreover, universal calibration does not always work for highly charged polymers. (Hagberg Decl., Ex. 5, Dubin Depo. at 96:12-16.) For these and other reasons, scientific publications in 1994 openly questioned and criticized the validity and accuracy of "so-called" universal calibration. (Hagberg Decl., Ex. 8, W. S. Bahary & M. Jilani, 48 *J. Appl. Polym. Sci.* 1531, 1531, 1537 (1993) (noting that "questions remain on its applicability in aqueous systems" and reporting experimental findings that universal calibration "was not always valid"); Ex. 6 at 37.) Indeed, Dr. Dubin admitted at his deposition that even "accurate" copolymer-1 molecular weight measurements using universal calibration in 1994 would require the user to accept up to a 20% error rate. (Hagberg Decl., Ex. 5, Dubin Depo. at 53:4-56:24.)

c. SEC Conditions Affect the "Electrostatic Interactions" That Frequently Distort SEC Measurements.

One reason that SEC standards and conditions are so important is that "electrostatic interactions" between the standard, polymer sample, and SEC column can produce significant distortions in SEC measurements. For example, charge repulsion between similarly charged elements will accelerate passage through an SEC column, while attraction between oppositely charged elements will result in delays; both effects distort the accuracy of SEC measurements. (Hagberg Decl., Ex. 9, P. Dubin, *Aqueous Size-Exclusion Chromatography*, Ch. 3 at 60 (1988); Hagberg Decl., Ex. 10, P. Dubin *et al.*, 635 *J. Chromatography* 51, 51-52 (1993); Hagberg Decl.,

Ex. 11, P. Dubin, 25 *Carbohydrate Polymers* 295, 295 (1994).) This well-documented phenomenon is one important reason why precise knowledge of SEC conditions is critical.

At the time of alleged invention, failed attempts at universal calibration had been attributed to electrostatic interactions. (Hagberg Decl., Ex. 8 at 1536-37.) Indeed, Teva's own expert, Dr. Dubin, has extensively documented these problems and their adverse impact on SEC analysis. In 1993, Dr. Dubin wrote that "[d]espite great technological progress in preparing SEC" columns, "it is difficult to ensure that the chromatography of a series of proteins is not affected by the unique electrostatic or hydrophobic interactions of the individual proteins with the packing." (Hagberg Decl., Ex. 10 at 51-52.) In 1994, Dr. Dubin published a similar paper reiterating these concerns, further noting that there was no easy solution because corrective adjustments to certain parameters such as pH often introduced new complications requiring further adjustments. (Hagberg Decl., Ex. 11 at 295, 300.)

Electrostatic interactions are potentially so troublesome that they can become the primary factor governing chromatographic separation in SEC analysis. (Hagberg Decl., Ex. 2 at 631.)

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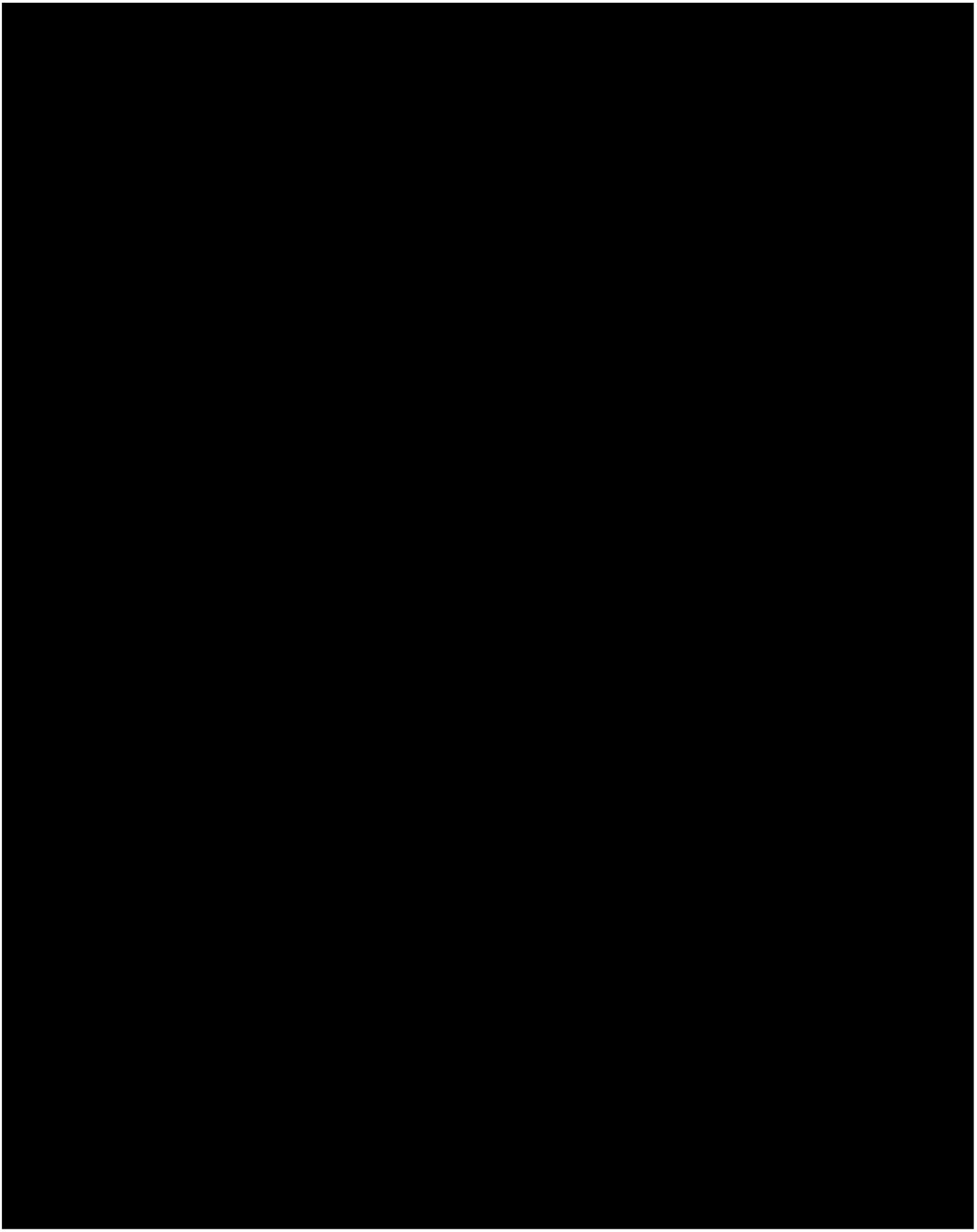

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3. Teva Has Publicly Emphasized the Importance of Precise and Accurate Molecular Weight Values for Copolymer-1.

Teva has repeatedly insisted in public statements that precise and accurate molecular weight values are crucial to the patentability and regulatory approval of copolymer-1. During patent prosecution, Teva overcame prior art by distinguishing the 9 kDa molecular weight recited in its claims from the 10 kDa molecular weight taught by the prior art. (Hagberg Decl., Ex. 16, 2/14/97 Office Action at 4.)[1] Thus, Teva obtained patent protection by convincing the Patent Office that a mere 1 kDa, or 10% difference, in molecular weight was sufficient to render the claimed copolymer-1 patentably distinct from the prior art. Teva is now bound by that position.

Teva also recently filed a Citizen Petition with FDA, requesting that the agency reject ANDAs for generic Copaxone because "even the most minor changes" in the molecular weight of copolymer-1 "will produce a new molecular entity" with drastic side effects including "organ damage" and "death." (Hagberg Decl., Ex. 17, FDA Citizen Petition at 15-16.) Teva insisted

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[1] Specifically, in a July 14, 1997 communication to the Patent Office, Teva argued that "the cited reference teaches a minimum molecular weight of 10 kilodaltons" and contrasted that precise molecular weight limitation with the claimed "copolymer-1 having a molecular weight of about 5 to 9 kilodaltons." Teva further argued that its invention "allows for the *precise* fractionation of copolymer-1 to produce a *particular* molecular weight range of copolymer-1," and contrasted this with the prior art which "does not teach or suggest specific fractionation . . . nor suggest any advantage to obtaining particular molecular weight fractions of copolymer-1." (*Id.*) (emphases added).

that the "unique complexity" of copolymer-1 left no margin for error, and that generic approval should require complete clinical trials to ensure safety.

B. Teva's Changing and Conflicting Expert Declarations

1. Claim Construction Expert Testimony by Dr. Grant

a. Dr. Grant's Original Declaration Testimony

Using a methodology involving hand-measurements, rough estimations, undefined error ranges, and unfounded assumptions, Dr. Grant submitted his first expert declaration asserting that a skilled artisan would implicitly understand Figure 1 as describing the "peak" molecular weight of copolymer-1. First, Dr. Grant visually inspected Figure 1 and hand-measured the location of the peaks on each curve. He compared his measurements (6.8 kDa and 11 kDa) to the numbers in Figure 1 (7.7 kDa and 12 kDa), and concluded that because his estimates were "close to th[e] numbers" in Figure 1, this "would support the assumption that the numbers in the legend were peak molecular weights." (Hagberg Decl., Ex. 18, D.I. 70 at 27-29.) He assumed that the numerical deviations between his hand-measurements and the actual numbers in Figure 1 were the result of unspecified peak shifts introduced during the data transformation process. His opinions based on these hand-measurements were stated as being within a "margin of error" – not an "acceptable margin of error," just a "margin of error." (Hagberg Decl., Ex. 1, 10/28/09 Grant Depo. at 96:9-101:4.)

b. Dr. Grant's Original Deposition Testimony

On October 28, 2009, Sandoz deposed Dr. Grant in connection with his claim construction declaration. At this deposition, Dr. Grant admitted the various assumptions, unknown errors, and undefined limitations on which his opinions were based.

First, Dr. Grant acknowledged that his methodology was inherently prone to multiple undefined errors. Specifically, Dr. Grant's conclusion is drawn primarily from the curves in

Figure 1, which he admitted "are not particularly rigorously-generated curves." (Hagberg Decl., Ex. 1, 10/28/09 Grant Depo. at 120:4-6.) He reiterated that the process of transforming Teva's original data to generate those curves would likely "cause a shift in the peaks," but he did not know the magnitude or direction of these shifts because he never considered Teva's original data in his analysis. (*Id.* at 103:24-105:10.) Dr. Grant also discussed the subjective components of his analysis, admitting that even his own peak measurements could vary because "[d]epending on where I personally pick[] the apex, . . . it could be lower, [or] it could be higher." (*Id.* at 106:21-107:2.) Indeed, Dr. Grant was asked to re-measure the curves in Figure 1 at his deposition, and he obtained different measurements than before, finding the second peak to be at 10 kDa instead of the 11 kDa originally reported in his declaration. (*Id.* at 115:24-117:12.) Dr. Grant confessed that a third measurement would likely produce yet a third, different number. (*Id.* at 117:11-12.)

Second, Dr. Grant could not specify a margin of error for his analysis. He would only say that his measurements were within an undefined "margin of error," and that he "did not state whether they were acceptable or not" but rather "simply stated that they existed." (*Id.* at 96:1-101:4.) When asked to elaborate further on the magnitude of this undefined "margin of error," Dr. Grant would only acknowledge that errors of 50%, 100%, 200%, and 2,000% all constituted a "margin of error" as he understood that term. (*Id.* at 97:3-23.)

Third, Dr. Grant repeated his belief that Figure 1 describes "peak" molecular weight simply because his hand-measured peaks of those curves are "close to" the numbers listed in Figure 1. He stated it was "appropriate to assume that [Figure 1] refers to peak molecular weights." (*Id.* at 102:19-20.) However, on further questioning, he admitted that peak molecular weight is "not actually an average" molecular weight, but instead "simply the molecular weight

at the peak" of a molecular weight curve. (*Id.* at 15:19-17:23.) Moreover, Dr. Grant admitted that the number-average (Mn) and weight-average (Mw) figures could have had the same value as Mp, but he had decided that Figure 1 does not describe Mn or Mw, based only on "generalities" involving the expected relationship between Mp, Mn, and Mw. (*Id.* at 128:7-129:9.) Dr. Grant further admitted he had not conducted "detailed calculations" of Mn or Mw because the "correct way to do it is from primary data," which he never examined or requested. (*Id.* at 126:5-24, 142:10-143:5.)

Fourth, Dr. Grant admitted that if Figure 1 were properly constructed, then the area under each curve should add up to 100 percent of molar mass. (*Id.* at 118:6-119:23.) Dr. Grant stated at his deposition that he did not know how to perform such calculations. (*Id.* at 118:6-10.)

[redacted]

Finally, Dr. Grant admitted that when conducting SEC, "[i]t is usually common practice that the conditions are stated and it is understood that those conditions must be met for reproducibility," because conditions such as flow rate, buffer, pH, salt, and packing density, can all affect the results of SEC analysis and result in different molecular weight values. (Hagberg Decl., Ex. 1, 10/28/09 Grant Depo. at 194:14-195:10.)

2. Dr. Grant's Supplemental Declarations

Following his first deposition, Dr. Grant submitted a series of supplemental declarations seeking to repair his admissions. *First*, after admitting that the area under each curve in Figure 1 should add up to 100 percent, Dr. Grant submitted a Second Supplemental Declaration insisting that "whether or not the area under each curve equals 100 percent is irrelevant." (Hagberg Decl., Ex. 19, D.I. 77 at 4.) *Second*, after admitting at his deposition that peak molecular weight "in truth [] is not a real average," Dr. Grant submitted a Third Supplemental Declaration insisting that peak molecular weight "is nevertheless an average" molecular weight. (Hagberg Decl., Ex. 20, D.I. 92 at 2.) *Third*, that same declaration also attempted to repair his prior admission regarding the area under Figure 1 by comparing Figure 1 to a pizza, arguing for the first time that the areas were "irrelevant" because they were all "relative." (*Id.* at 3.) *Finally*, Dr. Grant's Third Supplemental Declaration also attempted to repair his admission regarding the importance of SEC standards and conditions by advancing the circular argument that a skilled artisan could avoid incorrect measurements from inappropriate calibration standards and conditions, by

performing correct measurements using "appropriate calibration with appropriate standards." (*Id.*)

3. Teva's Summary Judgment Expert Testimony by Grant and Dubin

a. The Grant Declaration and Related Deposition

Dr. Grant's summary judgment declaration incorporates by reference each of his previously submitted declarations,[2] and proffers new testimony directly contradicted by his original deposition testimony. It is well-settled in this Circuit that "a party's affidavit which contradicts his own prior deposition testimony should be disregarded on a motion for summary judgment." *Mack v. United States*, 814 F.2d 120, 124 (2d Cir. 1987).

Here, Dr. Grant's declaration repeatedly contradicts his deposition testimony. *First*, regarding Figure 1, Dr. Grant incorporated his previous testimony that he measured the peak molecular weight to be 6.8 kDa and that this was close enough for him to conclude that Figure 1's label of 7.7 kDa "average molecular weight" was a reference to peak molecular weight. (Hagberg Decl., Ex. 18, D.I. 70 at 27, ¶ 62.) At his first deposition, Dr. Grant testified that he did not do any formal calculations of Mw or Mn to test his theory that 6.8 kDa was close enough to 7.7 kDa to conclude that the stated "average" was "peak" molecular weight (Mp). [redacted]

[2] Because Dr. Grant's summary judgment declaration incorporates by reference all of his previous Supplemental Declarations, and those Supplemental Declarations are directly contradicted by Dr. Grant's deposition testimony, Sandoz's present motion is directed at excluding the entirety of Dr. Grant's declaration testimony.

[redacted]

Second, after previously admitting that he does not know how to calculate the area under the curves in Figure 1, Dr. Grant's summary judgment declaration provides several pages and figures discussing how the Figure 1 curve may have been generated so its area could add up to 100%. (Hagberg Decl., Ex. 21, 1/22/2010 Grant Decl. at 4-12.) *Third*, Dr. Grant alleges for the first time that it would have been routine for a skilled artisan to use "universal calibration" to determine the molecular weight of copolymer-1, despite having failed to mention it as a relevant consideration during his first deposition. (*Id.* at 14.) *Fourth*, Dr. Grant also testifies that SEC analysis "does not depend on or require knowledge of the precise conditions used," despite admitting at his original deposition that these conditions can affect the outcome of SEC analysis. (*Id.* at 15.)

Finally, during his second deposition, Dr. Grant refused to articulate an objective standard or rate of error for his analysis of Figure 1, and finally admitted that "I can't put a limit on it" because an "objective opinion should be based upon real data" that he admittedly never requested or examined. (Hagberg Decl., Ex. 5, 2/2/10 Grant Depo. at 19:4, 22:9-11.)

[redacted]

b. The Dubin Declaration and Related Deposition

Dr. Dubin is a new Teva expert who supposedly has the same expertise as Dr. Grant, albeit without the prior inconsistent statements from prior declarations and depositions in this case. Dr. Dubin, like Dr. Grant, admits that he has no knowledge of what Teva actually did to measure the molecular weight of the copolymer-1 claimed in the asserted patents. [redacted]

Dr. Dubin, like Dr. Grant, also opines that it would have been routine for a skilled artisan to conduct SEC analysis of copolymer-1 using "appropriate" calibration standards, including either (1) "copolymer-1 itself", or alternatively (2) "universal calibration" using "any standards." (Hagberg Decl., Ex. 23, 1/22/10 Dubin Decl. at 6.) Unlike Dr. Grant, Dr. Dubin confessed at his deposition what Dr. Grant had refused to answer – that even the "appropriate" use of both universal calibration and the use of "absolute" measurements of copolymer-1 for use as standards, would still result in a 10-20% error. (Hagberg Decl., Ex. 5, Dubin Depo. at 53:4-16; 66:22-67:4.) Significantly, this error rate is unhelpful for a comparison to Teva's claims, in view

of the mere 10% difference in molecular weight that Teva previously relied on to distinguish its claims from the prior art.

III. LEGAL STANDARD

A. Burden of Proving Admissibility of Expert Testimony

The proponent of expert testimony must establish admissibility by a preponderance of the evidence. *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 593 (1993).

B. Relevance and Reliability Under *Daubert* and Federal Rule of Evidence 702

District courts are accorded considerable discretion in determining whether to accept expert testimony under Federal Rule of Evidence 702. *United States v. Roldan-Zapata*, 916 F.2d 795, 805 (2d Cir. 1990). District courts must ensure that expert testimony is both relevant and reliable. *Daubert*, 509 U.S. at 589. The inquiry into relevance requires the court to decide whether the expert's testimony will assist in understanding or determining a fact in issue, and whether the expert's testimony fits the facts of the case. *Id.* at 591.

Assessing the reliability of expert testimony properly includes considerations such as (1) whether the expert's technique can be tested; (2) whether the technique has been subject to peer review and publication; (3) the technique's known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; and (5) whether the technique has gained "general acceptance" in the relevant community. *Daubert*, 509 U.S. at 593-95.

Reliable expert testimony thus requires "a traceable, analytical basis in objective fact." *Bragdon v. Abbott*, 524 U.S. 624, 653 (1998). In addition, "reliability within the meaning of Rule 702 requires a sufficiently rigorous analytical connection between that methodology and the expert's conclusions." *Nimely v. City of New York*, 414 F.3d 381, 396 (2d Cir. 2005). Thus, expert testimony is properly excluded where it is "connected to existing data only by the *ipse*

dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *General Elec. Co v. Joiner*, 522 U.S. 136, 146 (1997).

C. Expert Testimony and Summary Judgment

On a motion for summary judgment, it is appropriate for the district court to decide questions regarding the admissibility of evidence, including expert opinion evidence. *Raskin v. Wyatt Co.*, 125 F.3d 55, 66 (2d Cir. 1997). If expert testimony is excluded, summary judgment is decided on a record that does not include that evidence, even where excluding the testimony would be outcome determinative. *Raskin*, 125 F.3d at 66-67; *Gen. Elec.*, 522 U.S. at 142-43.

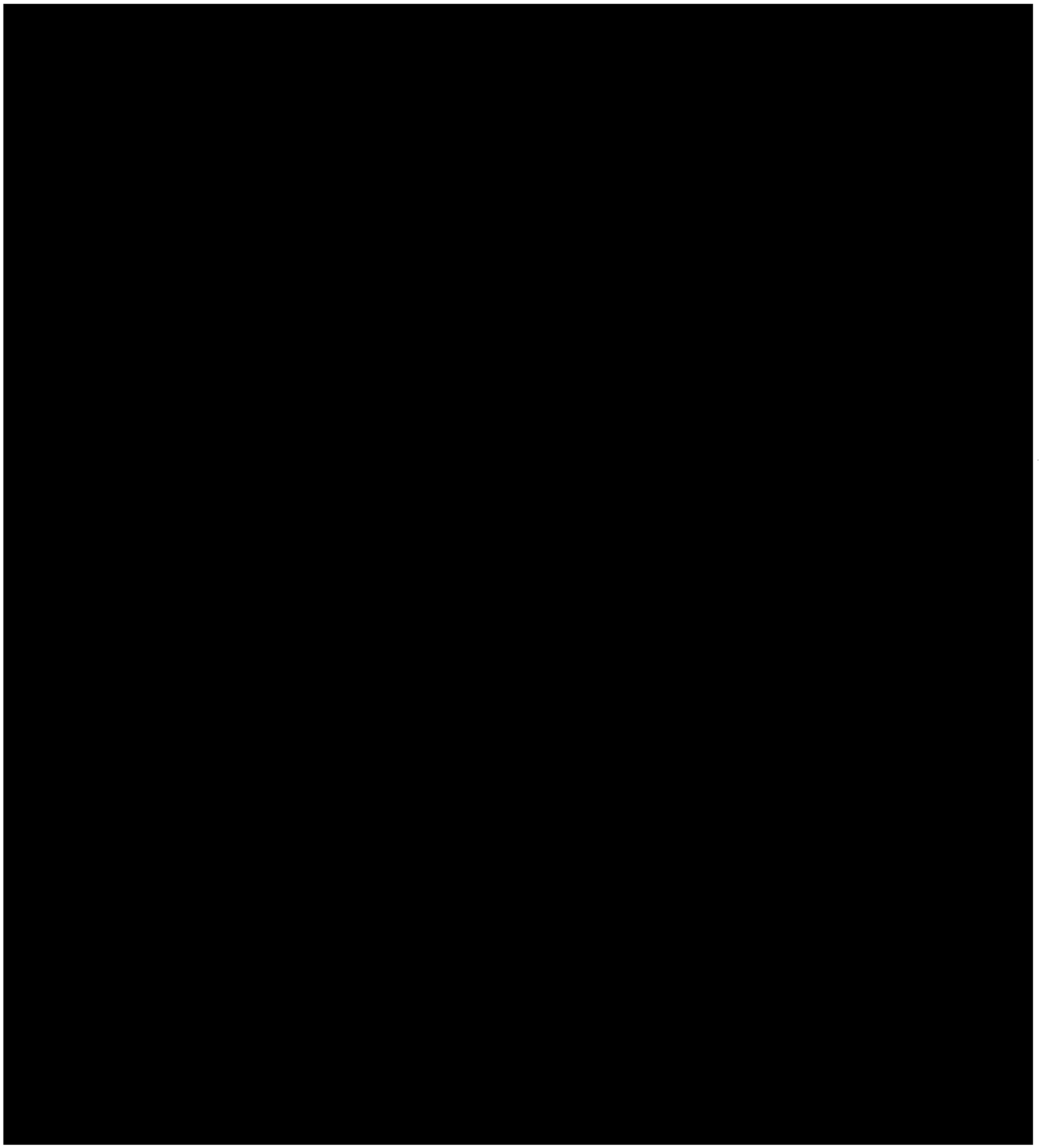
A party cannot create a genuine issue of fact sufficient to survive summary judgment simply by contradicting his or her own prior sworn testimony. *Cleveland v. Policy Mgmt. Sys. Corp.*, 526 U.S. 795, 806 (1999); *Hayes v. New York City Dep't of Corrections*, 84 F.3d 614, 619 (2d Cir. 1996) ("[F]actual issues created solely by an affidavit crafted to oppose a summary judgment motion are not 'genuine' issues for trial.").

IV. THE GRANT AND DUBIN DECLARATIONS FAIL TO SATISFY THE *DAUBERT* STANDARD FOR ADMISSIBLE EXPERT TESTIMONY.

A. Dr. Grant's and Dr. Dubin's Lack of Knowledge About What Teva Actually Did Renders Their Declarations Wholly Unreliable.

Expert testimony should be excluded when it is based on assumptions that are "so unrealistic and contradictory as to suggest bad faith." *Shatkin v. McDonnell Douglas Corp.*, 727 F.2d 202, 208 (2d Cir. 1984). Here, the record makes clear that Dr. Grant and Dr. Dubin have both based their opinions on unrealistic assumptions that completely ignore and contradict the evidence of Teva's analysis of copolymer-1. Because their testimony disregards "information that otherwise would tend to cast doubt on [their] theory" regarding the analysis of copolymer-1, Dr. Grant's and Dr. Dubin's declarations are "inherently suspect" and should be excluded. *In re*

Rezulin Prods. Liab. Litig., 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) (noting that selective expert opinions that do not adequately consider contrary evidence are unreliable).



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2. Dr. Grant's Opinion Involves Speculative Rationalization Rather Than Objective Analysis, Because He Never Examined Teva's Data.

Dr. Grant admits that he has never analyzed or even requested Teva's actual SEC data for copolymer-1, and thus he took no steps to verify his measurements against actual known data – the antithesis of scientific analysis. (Hagberg Decl., Ex. 4, 2/2/10 Grant Depo. at 20:2-3; 21:12-19.) Instead, Dr. Grant casually rationalizes the significant deviations between his hand-

[redacted]

measurements of the peaks (6.8 kDa) and the actual numbers in Figure 1 (7.7 kDa) by attributing them to undefined "peak shifts" of unknown magnitude and direction. This analysis is devoid of the intellectual rigor that is typically employed by scientists and required for admissibility. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) (*Daubert* requires that an expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field"); *Yaccarino v. Motor Coach Indus.*, No. 03-CV-4527 (CPS), 2006 U.S. Dist. LEXIS 97208, *51-52 (E.D.N.Y. Sept. 29, 2006) (testimony excluded where expert "took no steps to verify his admittedly 'rough calculations'").

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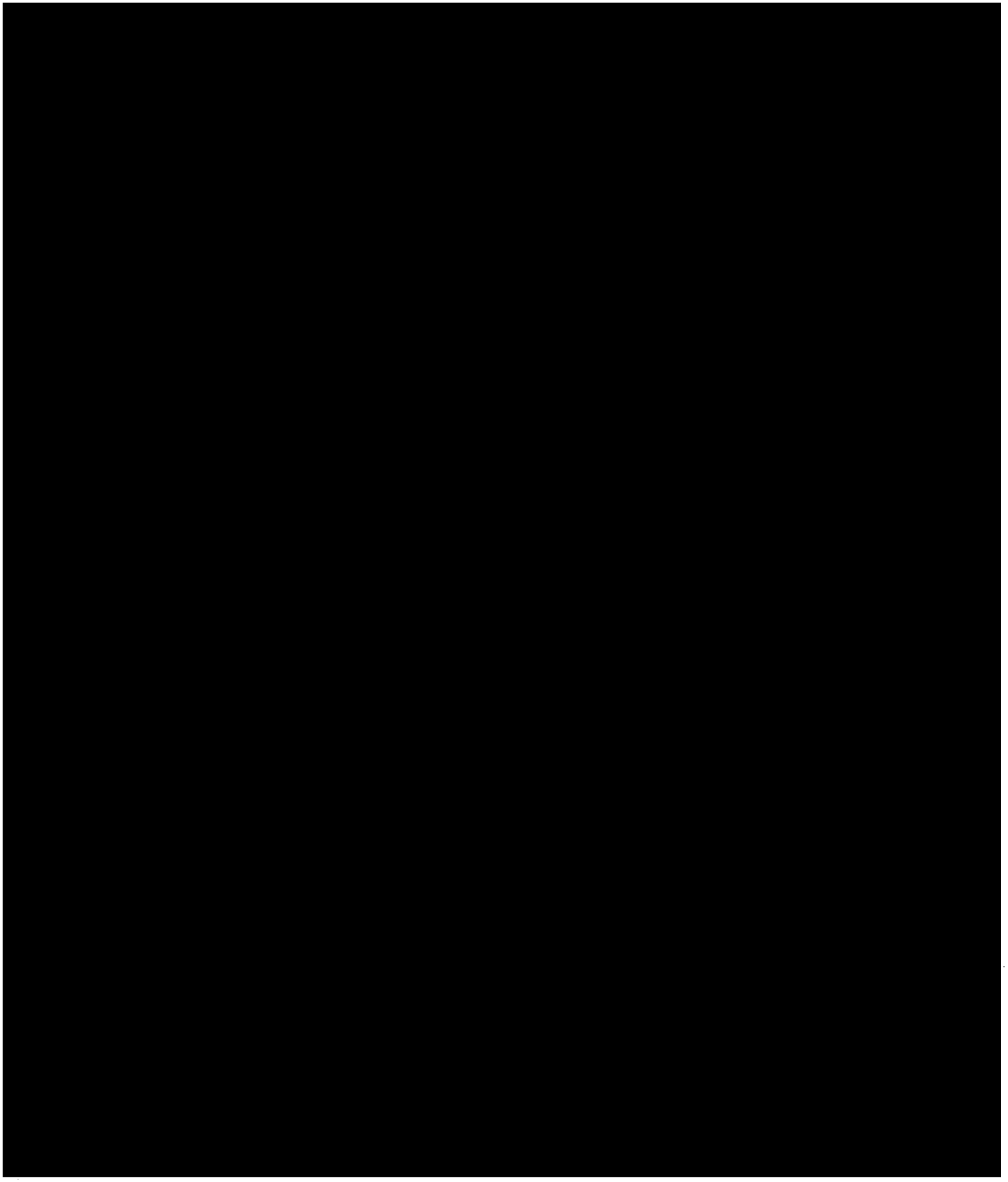


Second, SEC analysis of copolymer-1 would not have been routine due to the complications caused by electrostatic effects, as documented by Dr. Dubin's own scientific publications. Dr. Dubin wrote in 1988 that electrostatic effects are "pervasive" and "present on virtually all SEC packings," and because they "can dramatically affect" SEC measurements they "are undoubtedly important" but "may be difficult to isolate." (Hagberg Decl., Ex. 9 at 55, 60.) In 1993, Dr. Dubin continued to believe that "despite great technological progress" it was still "difficult to ensure" that SEC measurements were "not affected by the unique electrostatic or hydrophobic interactions" on the column. (Hagberg Decl., Ex. 10 at 51-52.) In 1994, he again described "a more serious problem" resulting from the "likelihood of interactions with the packing" and "it was not clear" that corrective measures such as pH adjustments would eliminate such interactions. (Hagberg Decl., Ex. 11 at 299-300.) Dr. Dubin's paid expert testimony stands in stark contrast to his pre-litigation, peer-reviewed publications, rendering his testimony unreliable.

5. The Grant and Dubin Declarations Address the Wrong Question.

Expert testimony must be relevant to be admissible. *Daubert*, 509 U.S. at 589. Sandoz's summary judgment motion addresses the proper question of indefiniteness: Can a skilled artisan meaningfully understand the precise scope of Teva's asserted claims? By contrast, Teva's experts only provide legally irrelevant testimony that skilled artisans would know what standards or conditions to use to accurately determine their own molecular weight. Teva sidesteps the critical inquiry of whether a skilled artisan could meaningfully compare the molecular weight of his or her copolymer-1 to the molecular weight values *as determined by Teva and recited in its claims* – i.e., using the same measurement standards and conditions as Teva. Teva's experts ignore this critical distinction, and instead invoke a meaningless "apples to oranges" comparison of molecular weight values determined using the skilled artisan's own standards and conditions

versus molecular weights values determined using *Teva's* unknown and undisclosed standards and conditions. Expert testimony based on irrelevant "apples and oranges" comparisons should be excluded. *Shatkin*, 727 F.2d at 208.

Likewise, even assuming for purposes of summary judgment that a skilled artisan could indeed properly conduct molecular weight determinations using copolymer-1 standards or universal calibration, this still would not salvage the indefiniteness of Teva's claims. This is because Dr. Dubin's acknowledged error rate for those techniques – up to 20% deviations in molecular weight by universal calibration and in the "absolute" measurement of molecular weight of "self-standards" – exceeds the 10% difference in molecular weight that Teva relied on in distinguishing its claims from the prior art. (Hagberg Decl., Ex. 5, Dubin Depo. at 52:7-56:24; 59:19-69:2.) Teva previously argued before the PTO that a mere 10% deviation (9 kDa v. 10 kDa) in molecular weight was patentably distinct from the prior art. Thus, a skilled artisan using either copolymer-1 standards or universal calibration still could not reliably assess potential infringement liability because the broad error rates inherent to those techniques exceed Teva's narrowly defined difference between its claims and the prior art. This technological inability to reliably distinguish between the molecular weights of Teva's claims and the prior art renders Teva's claims indefinite. *Morton Int'l v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993) (claims held indefinite where available analytical methods and equipment could not reliably analyze the claimed compound to assess potential infringement liability).

B. Dr. Grant's Analysis of Figure 1 is Deeply Flawed and Unreliable.

Dr. Grant's testimony that Figure 1 implicitly teaches "peak" molecular weight is inadmissible because he clearly has not "accounted adequately for obvious alternative explanations." *In re Rezulin*, 369 F. Supp. 2d at 425. Dr. Grant's own deposition testimony demonstrates an inexcusable failure to adequately consider the possibility that Figure 1 refers to

Second, Dr. Grant's testimony fails to satisfy any of the relevant *Daubert* factors. His methodology has not been tested or subjected to peer-review or publication; he has not articulated a meaningful error rate or objective standards to limit his analysis; and his technique is not generally accepted by the relevant scientific community. *Daubert*, 509 U.S. at 593-95.

Third, expert testimony must be reliable at every step, and should be excluded if any step renders the analysis unreliable. *Amorgianos v. Amtrak*, 303 F.3d 256, 267 (2d Cir. 2002). Here, the record reveals that Dr. Grant's analysis is *not* reliable at *any* step. The curves in Figure 1 are the foundation for Dr. Grant's analysis. He readily admits that these curves are not rigorously constructed, because the process of data transformation introduces "peak shifts" resulting in errors of unknown magnitude and direction. Dr. Grant's casual inspection and measurement of these loosely constructed curves, followed by cursory comparison to conclude that his measurements are "close to" the numbers in Figure 1, is the antithesis of reliability. This compounded uncertainty, coupled with Dr. Grant's inability or refusal to articulate an acceptable error rate or controlling standard, renders his opinion "so vague as to be meaningless." *Pretter v.*

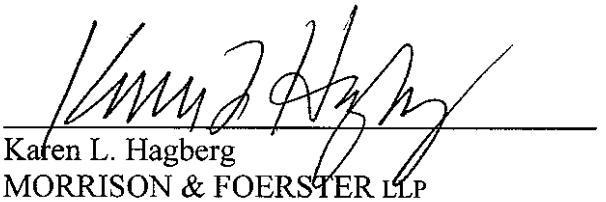
Metro N. Commuter R.R., 206 F. Supp. 2d 601, 603-04 (S.D.N.Y. 2002) (excluding expert opinion that "neither defined the[] factors with specificity nor offered objectively measured evidence" and instead "chose to rely on impressions and extrapolations derived from his brief and casual visual inspection").

V. CONCLUSION

Teva's opposition brief asks that this Court treat the contradictions and mistakes in the declarations of Drs. Grant and Dubin as an issue of credibility rather than admissibility. (Teva Oppo. MSJ Br. at 16.) "But the Federal Rules of Evidence require a greater degree of discrimination than that," and courts must resist "the temptation to answer objections to receipt of expert testimony with the shorthand remark that the jury will give it the weight it deserves." *Boucher v. U. S. Suzuki Motor Corp.*, 73 F.3d 18, 22 (2nd Cir. 1996) (internal quotations omitted). Courts in this district have routinely granted summary judgment where the non-moving party relies on allegedly disputed facts that are beyond reasonable belief. *See, e.g., Jeffreys v. Rossi*, 275 F. Supp. 2d 463, 478 (S.D.N.Y. 2003) (noting that "a party cannot rely upon implausible testimony to create a triable issue of fact"); *Schmidt v. Tremmel*, No. 93 Civ. 8588 (JSM), 1995 U.S. Dist. LEXIS 97, *10-11 (S.D.N.Y. Jan. 4, 1995) (granting summary judgment and finding no genuine issues of fact where a reasonable person would have to suspend disbelief to credit the non-moving party's allegations); *Price v. Worldvision Enters., Inc.*, 455 F. Supp. 252, 266 n.25 (S.D.N.Y. 1978) (acknowledging that "[i]ssues of credibility sufficient to defeat a motion for summary judgment are not created if the contradicting or impeaching evidence is 'too incredible to be believed by reasonable minds'"). The same reasoning and outcome should control here. [redacted]

For all the foregoing reasons, Dr. Grant's and Dr. Dubin's declarations should be stricken.

Dated: New York, New York
February 11, 2010

By: 

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